4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1992]

Marwan Massouh; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is denying Marwan Massouh's (Dr. Massouh's) request for a hearing and issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Dr. Massouh for 3 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Massouh was convicted of a misdemeanor under Federal law for causing the introduction or delivery for introduction into interstate commerce of drugs that were misbranded under the FD&C Act. Additionally, FDA finds that the conduct underlying Dr. Massouh's conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Dr. Massouh's debarment, FDA considered the relevant factors listed in the FD&C Act. Dr. Massouh failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Any application for termination of debarment by Dr. Massouh under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your

application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on https://www.regulations.gov.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All applications must include the Docket No. FDA-2018-N-1992. An application will be placed in the docket and, unless submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states

"THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240-402-5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if FDA finds that (1) the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and (2) the conduct underlying the conviction undermines the process for the regulation of drugs.

In September 2013, Dr. Massouh pled guilty to a misdemeanor for introducing a misbranded drug into interstate commerce, in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(a)). On October 16, 2013, the U.S. District Court for the Northern District of Ohio entered a judgment of conviction against Dr. Massouh for his violation of section 301(a) and sentenced him to 1 year of probation. According to the criminal information to which Dr. Massouh pled guilty, between January 3, 2006, and March 31, 2009, Dr. Massouh, an oncologist, purchased and received oncology drugs from a drug distributor located in Canada. Dr. Massouh's actions caused the introduction into interstate commerce of drugs that were misbranded under section 502(f)(1) of the FD&C Act (21 USC 352(f)(1)) because their labeling did not bear adequate directions for use.

By letter dated July 13, 2018, FDA's Office of Regulatory Affairs (ORA) notified Dr. Massouh of a proposal to debar him for 3 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal explained that FDA based the proposed debarment on his misdemeanor conviction. The proposal outlined findings concerning the four relevant factors that ORA considered in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the FD&C Act: (1) the nature and seriousness of the offense under section 306(c)(3)(A); (2) the nature and extent of management participation in the offense under section 306(c)(3)(B); (3) the nature and extent of voluntary steps to mitigate the impact on the public under section 306(c)(3)(C); and (4) prior convictions under the FD&C Act or other acts involving matters within FDA's jurisdiction under section 306(c)(3)(F). ORA found that the first two were unfavorable factors and the last two were favorable factors for Dr. Massouh. The notice concluded that "the unfavorable factors cumulatively outweigh the favorable factors and that debarment is appropriate."

The proposal offered Dr. Massouh the opportunity to request a hearing and provided him 30 days from the date of receipt of the letter to file the request and 60 days from the date of receipt of the letter to support his request with information sufficient to justify a hearing. In a

submission dated August 17, 2018, through counsel, Dr. Massouh "request[ed] a hearing relative to the Food and Drug Administration's Notice of Opportunity for Hearing" but did not include information to support his request. Further, Dr. Massouh did not state whether information justifying the hearing request would be forthcoming. However, more than 60 days have elapsed since Dr. Massouh's receipt of ORA's letter, and he has not filed any information, or any legal or policy arguments, to support his request.

Under the authority delegated to her by the Commissioner of Food and Drugs, the Acting Chief Scientist has considered Dr. Massouh's request for a hearing. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)).

Inasmuch as Dr. Massouh has not presented any information to support his hearing request, the Acting Chief Scientist concludes that Dr. Massouh has failed to raise a genuine and substantial issue of fact requiring a hearing. Therefore, the Acting Chief Scientist denies Dr. Massouh's request for a hearing. Further, Dr. Massouh has not presented any arguments concerning whether debarment is appropriate for his conviction or whether the proposed debarment period is appropriate. Based on the factual findings in the proposal to debar, the Acting Chief Scientist finds that a 3-year debarment period is appropriate.

II. Findings And Order

Therefore, the Acting Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under the authority delegated to her by the Commissioner of Food and Drugs, finds that (1) Dr. Massouh has been convicted of a misdemeanor under Federal law for causing the introduction into interstate commerce of prescription drugs that were misbranded under the FD&C Act and (2) that the conduct underlying the conviction undermines the process for the regulation of drugs. FDA considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a 3-year debarment is appropriate.

As a result of the foregoing findings, Dr. Massouh is debarred for 3 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (DATE of NOTICE), (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug application who knowingly uses the services of Dr. Massouh, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Massouh, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Massouh during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: April 21, 2022.

Jacqueline A. O'Shaughnessy,

Acting Chief Scientist.

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